

WO 01/06963

JC13 Rec'd PCT/PTO 25 JAN 2002

Orthopaedic Bone Cement  
Mixing Container

1ns  
AI

5 This invention relates to a container in which orthopaedic bone cement is mixed.

Orthopaedic bone cement is used throughout the world to secure hip, knee and other metallic prostheses in an appropriate anatomical position.

10 Many different systems are available for mixing orthopaedic bone cement and the type of apparatus selected will depend on the personal preferences of the doctor or nurse mixing the cement, as well as the amount of cement being mixed and the type of materials being used.

15 Essentially, orthopaedic cement is made up of a powder component, e. g. polymethylmethacrylate powder, and a monomer, eg. g. methylmethacrylate monomer liquid, generally provided in an ampoule which is broken and added to the powder. The two components are then  
20 thoroughly mixed to provide a malleable cement which can be manipulated and applied to the appropriate bone parts, during surgery.

In order to avoid the cement becoming brittle, it is essential that the two components are very thoroughly  
25 mixed together and no 'dry' or 'dead' spots remain. Furthermore, as most cements set fairly quickly, it is important that the mixing can be quickly and easily carried out. This is, also, of course important as surgery should be carried out as quickly as possible for  
30 the comfort and safety of the patient.

Originally, the cement components were mixed, by hand, using a bowl and spatula. A theatre nurse would mix the appropriate quantities of the two components in the bowl and the physician would then take some of the  
35 mixed cement and mould it to the required shape, before inserting it into a preformed cavity or applying it to a resected bony surface where the prosthesis is to be



WO 01/06963

- 3 -

One such mixing device is the bowl mixer forming the subject of European Patent No. 0616552. This system is preferred by many users as it is small and convenient to use and the mixing action is similar to that carried out in the above described manual bowl mixing technique and is one with which nurses are generally familiar.

Another mixing system is described in European Patent No. 0744991. In this arrangement, the cement is mixed in a cylindrical mixing chamber. The mixing mechanism comprises paddles rotatably mounted within the chamber. The paddles are rotated around the chamber by means of a 'barley twist' mechanism so that the user merely has to push the handle up and down, to cause rotation of the paddle. Furthermore, once the cement is mixed, this system can be converted into a syringe type dispenser by addition of a nozzle and plunger. There is thus no need to remove the mixed cement from the mixing chamber and transfer it to a dispenser.

Other similar mixing arrangements are known.

In all of these systems, the cement components need to be put into the mixing chamber. Generally, the nurse is provided with the cement powder, in a bag, and monomer ampoule. These are opened by the nurse, manually, and are introduced into the mixing chamber or bowl by means of funnels.

One problem is that when cutting open the cement powder bag and inserting the powder via the funnel, there is a certain degree of wastage due to spillage and cement clinging to the funnel. Furthermore, the opening and pouring of the cement powder caused a powder cloud which, within the regulated confines of the operating theatre, is unpleasant and may even have adverse effects on the theatre personnel.

These problems become more acute when time is very short and the mixing must be done extremely quickly, or with inexperienced theatre personnel.

One solution which has been considered is to

WO 01/06963

- 4 -

provide a pre-filled mixing apparatus, wherein the disposable mixer, for example a bowl mixer or syringe mixer as described above, is supplied already containing the cement powder in the mixing chamber. This generally makes things much easier for the theatre nurse when needing to mix the cement quickly during an operation.

However, tests have shown that if the cement powder is housed within the mixing chamber or bowl and contained therein by means of a cap, the powder moves about, particularly during transportation, and covers the entire internal surface area of the mixing chamber and the lid. When the mixing is carried out, with the introduction of the monomer, unmixed powder remains at the top of the mixing vessel due to the monomer not wetting all of the walled surface, and the mixing paddle not reaching the very fine layer of powder on the walls and at the top of the chamber. Thus, powder is wasted and 'dry' spots occur, resulting in brittle cement which can have adverse consequences.

The aim of the present invention is to provide a pre-filled orthopaedic cement mixing apparatus in which the above mentioned problems are overcome.

*a 145 A22* **SUMMARY OF THE INVENTION**  
According to one aspect of the present invention, there is provided an apparatus for containing and mixing orthopaedic cement, the apparatus containing an outer housing defining a mixing chamber and an inner housing containing the cement prior to mixing, wherein the inner housing is removable from the outer housing such that the cement remains in the mixing chamber.

In accordance with another aspect of the invention, there is provided a method of providing and mixing of orthopaedic cement comprising sealing said cement in an inner housing; disposing said inner housing within an outer housing which defines a mixing chamber; removing the inner housing, leaving the cement in the mixing chamber for mixing.

The present invention may be incorporated into any

WO 01/06963

- 5 -

known cement mixing arrangements including the bowl mixer and syringe mixer described above. It may also be incorporated in mixing bowls where the mixing is carried out simply using a spatula etc.

5 The inner housing may be removable from the outer housing in any way, for example it may be in the form of a bag which is merely lifted out by the user, which opens on removal to drop the cement powder into the mixing chamber. In the most preferred embodiment, however, the inner housing is attached to or formed integrally with a lid provided on the container. The inner housing and the lid may, for example, be attached to each other by a snap fit arrangement or, indeed, by any other means of attachment. Thus, when the cement is to be mixed, the lid is removed by the user and as the lid is removed, it takes with it the inner housing.

10 To provide a secure container during transportation etc., the lid is preferably attached to the outer housing by means of a screw thread. Seals may also be provided.

20 The inner housing may be made of any materials suitable for containing the cement powder. Preferably, the material of which the inner housing is made is less rigid than that of the outer housing. This allows the inner housing to be compressed against the outer housing to provide a good seal at the open end of the inner housing.

25 It is important that, prior to removal of the inner housing, the cement is securely contained within the housing and, therefore, the 'open' end of the inner housing should form a seal with the outer housing or should be closed after filling.

30 Thus, in one embodiment, not shown, the inner housing has an open end into which the cement is inserted. This open end is then closed by any suitable means and the inner housing is placed within the outer housing in such a manner that when the inner housing is



WO 01/06963

- 7 -

fit arrangement 6. This creates a seal through which the cement powder cannot pass.

Fig. 2A shows how the cement is inserted into the inner housing, via the open end 7 of the housing.

5 The outer housing 3 incorporating the piston and base 8 is then fitted over the cement containing inner housing as shown in Fig. 2D.

10 Guide lips 9 may be provided on the outer surface of the inner housing to assist in the correct positioning of the outer housing relative to the inner housing.

The outer housing is then secured to the cap, by means of a screw thread 10, as shown in Fig. 2C. The open end of the inner housing, containing the cement, is provided with a seal 11, preferably a feather seal, which fully seals to the piston part of the outer housing to secure the cement powder within the inner housing. This results in a fully sealed packaged container, containing the cement powder within the inner housing, ready for use. The whole device is then packaged and sterilised for use.

20 A breather pad (not shown) may be provided on the cap so as to allow gas circulation to the cement.

25 As shown in Fig. 2D, when the cement is to be mixed, the user unscrews the cap 5 from the outer housing 2 and lifts away the cap and the inner housing 3 connected thereto. As the inner housing is lifted away from the base of the outer housing, the cement powder 4 drops out of the inner housing into the mixing chamber 1. The cap and inner housing are then discarded and the standard mixing procedure for this type of mixing arrangement is carried out.

35 A similar procedure is used in relation to other mixing arrangements such as the bowl mixer 12 shown in Fig. 3. This may be a bowl as described in EP 0616552. The principle is essentially the same. An inner housing 3', containing the cement powder 4', is attached to the

WO 01/06963

- 8 -

5 lid 5' of the bowl at one end and is sealed 11' to the base of the bowl or the sides of the bowl near its base by means of e. g. a feather seal. In use, the lid 5' and attached inner housing 3' are removed, such that the cement powder 4' drops out of the inner housing into the mixing chamber 1' and mixing is carried out in the usual way.

10 It is preferable that the inner housing is made of a material which is less rigid than the outer housing. This allows the feather seal edge of the inner housing to be compressed unto the outer housing to provide a secure seal for the cement powder.

15 In the preferred syringe type arrangement, the inner housing is designed to hold up to 80g of cement powder, i. e. a double mix of cement. In the case of the bowl mixer, preferably, the inner housing can hold up to 120g, i. e. a triple mix of cement.

20 Because the cement powder is contained within the inner housing until it is to be mixed, and is then dropped out of the housing only into the bottom of the mixing chamber, no cement clings to the upper outer walls of the mixing chamber and so practically all of the cement can be thoroughly mixed, producing a high quality mixed orthopaedic cement.

25